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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte ASSAF GOVARI, ANDRES CLAUDIO ALTMANN, and ALEXANDER LEVIN[1]

Appeal 2015-002463
Application 12/129,012
Technology Center 1600

Before ERIC B. GRIMES, ULRIKE W. JENKS, and ROBERT A. POLLOCK, *Administrative Patent Judges*.

JENKS, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a method and system for tracking the position of an internal probe with a reference probe. The Examiner rejects the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

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[1] According to Appellants, the Real Party in Interest is Biosense Webster (Israel) Ltd. Br. 1.

STATEMENT OF THE CASE

According to the Specification:

> In intracardiac tracking systems, such as CARTO™ (produced by Biosense Webster, Diamond Bar, California), the position coordinates of a catheter inside the heart are determined relative to a reference location outside the patient's body. In CARTO, for example, both the catheter and a reference pad under the patient's back contain miniature coils, which sense the amplitude and direction of a magnetic field. As the patient breathes, however, the resulting movement of the patient's thorax causes the heart to shift position relative to the reference pad, so that the coordinates of the catheter will change during the respiratory cycle even while the catheter is stationary relative to the heart.

Spec. 1:15–27. By placing a reference probe inside the heart so that "[t]he reference probe is held stationary and serves as a reference point for measuring the relative coordinates of the active device" the effect of respiration on the coordinates of the active device can be largely eliminated. Spec. 2:14–16.

Claims 1–6, 8–15, 17, and 18 are on appeal, and can be found in the Claims Appendix of the Appeal Brief. Claim 1 is representative of the claims on appeal, and reads as follows (emphasis and numbering added):

> Claim 1. A method for position tracking, comprising:
>
> placing an internal reference probe, which comprises a first position transducer, in a fixed reference location within a heart of a subject;
>
> collecting and processing first location coordinates of the internal reference probe in an externally fixed frame of reference, using the first position transducer, during one or more respiratory cycles of the subject so as to define a first range of the location coordinates corresponding to the reference location of the internal reference probe;

establishing a permitted threshold for a deviation of the location coordinates from the first range;

inserting an active device, which comprises a second position transducer, into the heart;

collecting second location coordinates of the active device in the externally fixed frame of reference, using the second position transducer, and jointly processing the first location coordinates and the second location coordinates so as to find relative location coordinates of the active device in a cardiac frame of reference;

after defining the first range of the location coordinates corresponding to the reference location, upon detecting a deviation of the first location coordinates from the first range_that is more than the permitted threshold, establishing a second range of location coordinates corresponding to the reference location that are outside of the first range and more than the permitted threshold and

establishing a correction vector based on the deviation of the location coordinates of the first range, thereby identifying a displacement of the reference probe from the fixed reference location; and

correcting the relative location coordinates of the active device in the cardiac frame of reference using the correction vector so as to compensate for the displacement.

The following grounds of rejection are before us for review:

The Examiner rejects the claims as follows:

I. claims 1, 3–6, 8–15, 17, and 18 under 35 U.S.C. § 103(a) as unpatentable over Dukesherer[2] in view of Smith[3] in view of Lu;[4] and

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[2] Dukesherer et al., US 2005/0085715 A1, published Apr. 1, 2005 ("Dukesherer").
[3] Smith et al., US 5,515,853, issued May 14, 1996 ("Smith").
[4] Lu et al., US 2007/0201613 A1, published Aug. 30, 2007 ("Lu").

II. claims 2 and 11 under 35 U.S.C. § 103(a) as unpatentable over Dukesherer, Smith, and Lu and further in view of Slettenmark.[5]

Since both of these rejections rely upon the teaching of Dukesherer, Smith, and Lu regarding the use of probes for the purpose of determining the location of an active probe that is located in a cardiac reference frame and correcting the coordinate location of the active probe in the frame, the same issue is dispositive for both of these rejections, so we will consider the rejections together. As Appellants do not argue the claims separately, we focus our analysis on claim 1, and claims 2–6, 8–15, 17, and 18 stand or fall with that claim. 37 C.F.R. § 41.37 (c)(1)(iv).

The Examiner finds that Dukesherer teaches the use of a catheter and at least one reference probe. *See* Ans. 2–4. According to the Examiner Dukesherer teaches the use of a fixed frame reference probe 54 "for collecting and processing first location coordinates of the internal reference probe [] with respect to the fixed frame of reference, using the first position transducer." Ans. 3. Although Dukesherer teaches that the reference frame 54 can be attached externally as well as internally (Dukesherer ¶¶ 55 and 56), "Dukesherer does not suggest specifically that the dynamic reference frame (54) may be placed attached to both internal and external regions of the patient's body." Ans. 4. The Examiner relies on Smith for teaching the use "of both an internal reference frame and an external reference frame for tracking of an [] object such a catheter device inserted into a patient." Ans. 4. The Examiner acknowledges that the combination of Dukesherer

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[5] Slettenmark, US 6,266,552 B1, issued July 24, 2001.

and Smith does not teach establishing a "threshold for a deviation of the location coordinates" and looks to Lu for providing this teaching. Ans. 4. With respect to the correction vector, the Examiner finds that Dukesherer teaches "'comparison between two sets of points'" Ans. 5, citing Dukesherer ¶63. The Examiner explains that

> comparison between two points of interest would provide movement information which would include speed, direction, etc. as it would be understood reasonably by one of ordinary skill in the art that body or anatomical movement of patient would include these parameters), thereby identifying a displacement of the reference probe (i.e. internal dynamic frame, 54) from the fixed reference location (as described by Dukesherer in paragraph [0065]); and correcting the relative location coordinates of the active device in the cardiac frame of reference using the correction vector so as to compensate for the displacement (Dukesherer: [0065]; Lu: paragraph [0083]).

Ans. 5–6. In other words, the Examiner's position is that the reference teaches correcting the images on the display in response to the movement of the reference frame in relation to the coil array, where "[t]his relative motion is communicated to the coil array controller 48, via the navigation probe interface 50, which updates the registration correlation to thereby maintain accurate navigation." Dukesherer ¶65.

Appellants contend that neither Dukesherer, Smith, nor Lu either alone or in combination teach all the claimed elements. Br. 4–6. Appellants contend that there is no suggestion or motivation in the art to modify Dukesherer, because even when combined with the other references there are no first and second range of location coordinates and the resulting combination would not disclose using a vector in any way. Br. 6–10. According to Appellants, Dukesherer "merely teaches the use of multiple dynamic reference frames 54 to compensate for movement based purely on assumption using a rudimentary weighting technique and not at all based on a correction vector." Br. 10. Specifically noting that the "weighting technique [is] based on the assumption that certain parts of the body 'move more than others' and, as such, those respective body parts are weighted accordingly." Br. 11. Appellants contend that Lu has nothing to do with determining the location of a probe. Lu simply "teaches compensating for such deviations in motion (due to breathing) merely using 'tracks'" and these tracks have "absolutely no relation to the correction vectors distinctly claimed." Br. 13.

The issue is: Does the preponderance of evidence of record support the Examiner's conclusion that the combination of references renders the claimed method of position tracking an active device in the heart of a subject obvious?

Findings of Fact

FF1. Dukesherer teaches a surgical navigation system that utilizes a dynamic reference frame. Figure 1 is reproduced below:

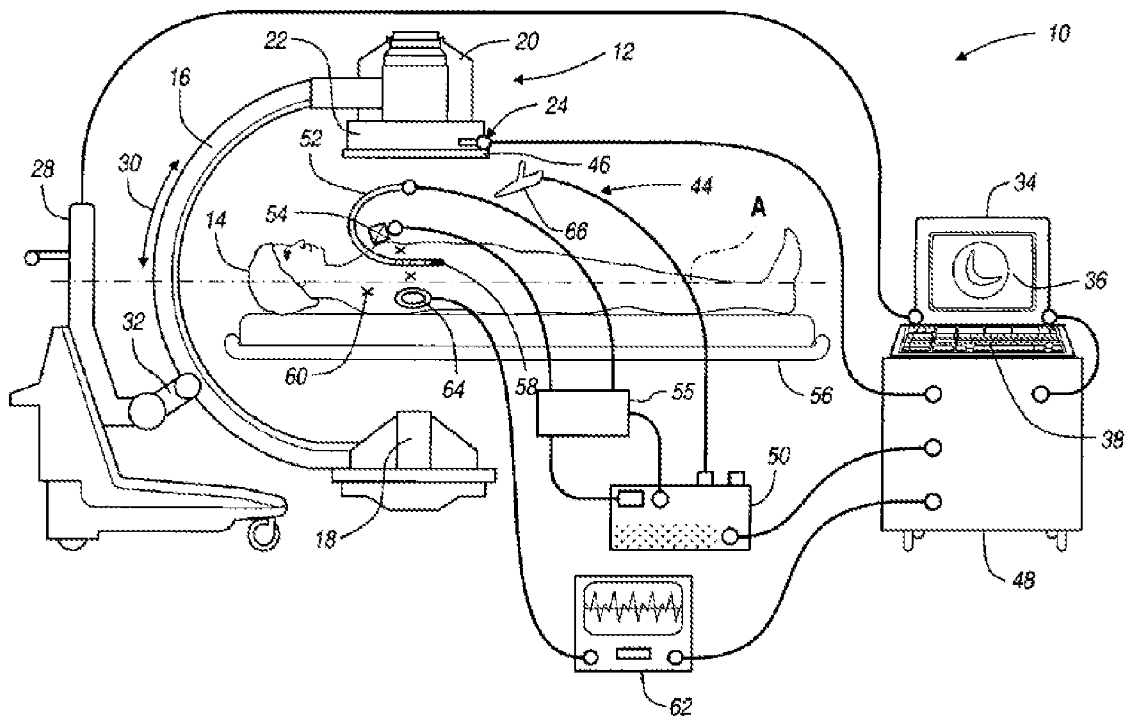

Figure 1 is a diagram of a navigation system that shows instrument 52 with sensor 58, a dynamic reference frame 54, the electromagnetic tracking system 44, a transmitter coil array 46, a coil array controller 48, and a display 36. ¶¶52–66. The system also includes an x-ray source 18, an x-ray receiving section 20, an optional calibration and tracking target 22 and optional radiation sensors 24. ¶35.

FF2. Dukesherer teaches that, after the insertion of a catheter into a patient,

> the position of the instrument is displayed on the display 36 and is not generally viewable by a user because it is within the cavity of the patient 14. Therefore, the user is

> generally dependent upon the accuracy of the display 36 to ensure the proper location, orientation and other attributes of the instrument relative to the patient 14. For example, . . . the instrument 52, such as the catheter, is positioned relative to a specific portion of a heart of the patient 14.

Dukesherer ¶115, *see also* ¶¶52–66. "[T]he electromagnetic tracking system 44 can determine the position of the catheter 52 by measuring the field strength at the sensor 58 location." Dukesherer ¶62.

FF3. Dukesherer teaches "the dynamic reference frame 54 may be *internally attached*, for example, to the wall of the *patient's heart* or other soft tissue using a temporary lead that is attached directly to the heart. This provides increased accuracy since this lead may track the regional motion of the heart." Dukesherer ¶56 (emphasis added). "It should further be noted that multiple dynamic reference frames 54 may also be employed." Dukesherer ¶57.

FF4. The dynamic reference frame 54 of Dukesherer

> is a small magnetic field detector that is designed to be fixed to the patient 14 adjacent to the region being navigated so that any movement of the patient 14 is detected as relative motion between the transmitter coil array 46 and the dynamic reference frame 54. This relative motion is forwarded to the coil array controller 48, which updates registration correlation and maintains accurate navigation.

Dukesherer ¶55; *see* ¶ 65. "[T]he dynamic reference frame 54 may be used to ensure that any planned or unplanned movement of the patient or the receiver array 46 is determined and used to correct the image on the display 36." Dukesherer ¶66.

FF5. Dukesherer teaches that the navigation field is a low energy magnetic field that allows for the tracking system to

> the electromagnetic tracking system 44 can determine the position of the catheter 52 by measuring the field strength at the sensor 58 location. The dynamic reference frame 54 is fixed to the patient 14 to identify the location of the patient in the navigation field. The electromagnetic tracking system 44 continuously recomputes the relative position of the dynamic reference frame 54 and the catheter 52 and relates this spatial information to patient registration data to enable image guidance of the catheter 52 within the patient 14.

Dukesherer ¶62.

FF6. Dukesherer teaches that "[r]espiration and cardiac motion can cause movement of cardiac structures relative to the instrument 52." Dukesherer ¶58. Allowing for image acquisition at the same point in the movement phase is achieved "[b]y time-gating or event gating at a point in a cycle the image data and/or the navigation data, the icon of the location of the catheter 52 relative to the heart at the same point in the cardiac cycle may be displayed on the display 36." Dukesherer ¶58.

FF7. Dukesherer teaches that

> navigation system 10 analyzes the relationship between the two sets of points that are selected and computes a match, which correlates every point in the image data with its corresponding point on the patient's anatomy or the patient space. The points that are selected to perform registration are the fiducial markers or landmarks 60, such as anatomical landmarks. Again, the landmarks or fiducial points 60 are identifiable on the images and identifiable and accessible on the patient 14. The landmarks 60 can be artificial landmarks 60 that are positioned on the patient

> 14 or anatomical landmarks that can be easily identified in the image data. The artificial landmarks, such as the fiducial markers 60, can also form part of the dynamic reference frame 54.

Dukesherer ¶63.

FF8. Smith discloses "[a] method and apparatus for simultaneous measurement of multiple distances by means of networked piezoelectric transducers." Smith, Abstract. Smith teaches:

> The basic principle of the Catheter Guidance System (CGS) of the present invention involves the establishment of an internal reference frame and an (optional) external reference frame in three dimensions from which the catheter can be traced. Using the transceiver hardware and the triangulation algorithm discussed above, the crystal positioning data can be captured and processed to resolve the location of the catheter of interest.

Id. at 12:30–37; *see also* 15:29–33 ("A further application of the tracking system according to the present invention involves placing reference crystals anywhere on the patient's head, and an active crystal on the tip of the probe. As the probe is inserted into the head, its movement relative to the reference crystals can be tracked in real time 3-D").

FF9. Lu teaches that real time tracking of the position of an internal tumor is important in extending radiation therapy to a patient. Lu teaches "a method of treating a moving target, such as a tumor of a lung, can include 'gating,' or delivering radiation only when the target is within a specified window of trajectory." Lu ¶ 2. Lu also teaches breathing synchronized delivery ("BSD"), a technique that "utilizes an anticipated track, or path of motion, for a target to follow during treatment." Lu ¶3.

> [G]ating, tracking, BSD, or the free-breathing delivery ("FBD") technique, [each] require[s] the real time knowledge of the breathing states, or at least the tumor position. Some available respiratory monitoring techniques include marker methods and airflow methods. Both methods indirectly monitor respiratory motion by some kind of surrogate. The marker methods use external or internal markers as the surrogate.

Lu ¶63

FF10. Lu teaches that when applying radiation therapy to regions that are moving, for example due to respiration,

> [t]he software program . . . [tracks] anticipated motion (e.g., the patient's breathing pattern). The treatment plans are optimized (block 178) by the optimization module 95 to correspond to the tracks 102-130. . . . The plan selection module 142 can compare the deviation to a range to determine if the deviation is greater than a specified threshold. The plan selection module 142 determines (block 198) which track 102-130 the motion most closely[] presently corresponds. The plan selection module 142 selects (block 202) the treatment plan that corresponds to the identified track 102-130. The patient's treatment can include delivery of portions of a plurality of treatment plans as the selected plan can automatically switch to correspond to the patient's actual motion.

Id. ¶83

Principle of Law

"If the claim extends to what is obvious, it is invalid under § 103." *KSR Int'l Co. v. Teleflex Inc.,* 550 U.S. 398, 419 (2007).

Analysis

Dukesherer teaches a reference probe 54 and an instrument 52, such as a catheter. FF1–FF3. The instrument contains a sensor 58 that can indicate the position of the instrument 52 in the electromagnetic field. FF5Dukesherer teaches the processing of motion between the transmitter coil 46 and reference frame 54 that measures any planned and unplanned movement of the patient as well as establish the location of the patient in the navigation field. FF4 and FF5. "The electromagnetic tracking system 44 continuously recomputes the relative position of the dynamic reference frame 54 and the catheter 52 during localization." FF5. Thus, the tracking system computes the location of reference frame 54 and the instrument 52 as they are positioned in the electromagnetic field 46, and positions them not only in relation to each but also in relation to the patient. FF4 and FF5. Dukesherer teaches that the reference frame 54 may be placed externally, as well as internally into the heart. FF3. Dukesherer also teaches, but does not exemplify, the use of more than one reference frame 54 in a patient. FF3. Dukesherer recognizes that respiration and heart rhythm result in motion of the reference frame as well as device 52 while they are positioned in the heart. FF6. Dukesherer teaches using a gating technique in order to time the location acquisition data to the same point in the cardiac cycle. FF6.

Smith teaches a catheter guidance system that uses external as well as internal reference frames that allow for the three dimensional positioning of the catheter using triangulation algorithms. FF8.

Lu teaches determining the location of a tumor based on the anticipated location of the tumor during a respiration cycle in order to program a device to continuously deliver radiotherapy to the tumor. FF9 and FF10. To achieve this Lu utilizes a software program that tracks the anticipated motion and sets deviation ranges. FF10. Lu's program will select a treatment plan that most closely resembles the detected motion in the patient. FF10.

The Examiner finds that Dukesherer teaches most of the claimed elements but recognizes that "Dukesherer does not suggest specifically that the dynamic reference frame (54) may be placed [and] attached to both internal and external regions of the patient's body," and relies on Smith for teaching "both an internal reference frame and an external reference frame for tracking of an [] object." Ans. 4. The Examiner also acknowledges that Dukesherer and Smith do "not suggest specifically 'establishing a permitted threshold for a deviation of the location coordinates from the first range.'" Ans. 4. The Examiner relies on Lu to establish setting deviation parameters for tracking patient movement. Ans. 4. The Examiner concludes that it would have been obvious

> to modify the tracking patient movement with external and internal reference frame teachings of Dukesherer in view of Smith with the establishment of permitted threshold for a deviation of the location coordinates from the first range with respect to tracked patient movement teachings of Lu to "promote a more consistent track" (Lu: [0083]) or movement of catheter within the patient's body.

Ans. 4

We have reviewed Appellants' contentions that the Examiner erred in rejecting claims 1–6, 8–15, 17, and 18 as obvious over the cited art. Br. 4–14. We disagree with Appellants' contentions and adopt the findings concerning the scope and content of the prior art set forth in the Examiner's

Answer and the Final Rejection dated April 9, 2014. We address Appellants' contentions below.

Appellants contend that the combined teachings of Dukesherer, Smith, and Lu, "does not disclose using a vector in any way." Br. 10. According to Appellants, Dukesherer "merely teaches the use of multiple dynamic reference frames 54 to compensate for movement based purely on assumption using a rudimentary weighting technique and not at all based on a correction vector." Br. 10. Appellants argue that Dukesherer teaches "a weighting technique based on the assumption that certain parts of the body 'move more than others' and, as such, those respective body parts are weighted accordingly." Br. 11. Appellants contend that Lu has nothing to do with determining location coordinates and the "reference merely teaches compensating for [] deviations in motion (due to breathing) [by] merely using "tracks"" and these tracks have "absolutely no relation to the correction vectors distinctly claimed." Br. 13.

We are not persuaded. As the Examiner explained, Dukesherer teaches

> "comparison between two sets of points," [0063]; comparison between two points of interest would provide movement information which would include speed, direction, etc., as it would be understood reasonably by one of ordinary skill in the art that body or anatomical movement of patient would include these parameters), thereby identifying a displacement of the reference probe (i.e. internal dynamic frame, 54) from the fixed reference location (as described by Dukesherer in paragraph [0065]); and correcting the relative location coordinates of the active device in the cardiac frame of reference using the

> correction vector so as to compensate for the displacement (Dukesherer: [0065]; Lu: paragraph [0083]).

Ans. 14. We agree with the Examiner that correcting the relative location coordinates of the instrument in the cardiac frame of reference, in other words on the display, would inherently require the use of a calculated correction. Dukesherer specifically discloses tracking unplanned movement between transmitter coil 46 and reference frame 54 and correcting the image on the display. FF4. Dukesherer also discloses tracking of the catheter 52 based on the field strength 58 and the dynamic reference frame 54 to identify the location of the catheter in the reference frame of the patient. FF5. Dukesherer's "electromagnetic tracking system 44 continuously recomputes the relative position of the dynamic reference frame 54 and the catheter 52." FF5. Although Dukesherer continuously calculates the position of the catheter based on the reference frame and pre-set landmarks, the reference is silent with respect to what calculations are being applied. Smith teaches that one way to track the position of a catheter in a patient is to apply a triangulation algorithm to data from internal and external reference frames. FF8; *see* Ans. 10. We agree with the Examiner's position that calculating the displacement of a reference probe as well as the location of the catheter using a fixed reference frame as taught by Dukesherer within the electromagnetic field would reasonably encompass vector correction via triangulation to compensate for such displacement as suggested by Smith.

Appellants contend that neither Dukesherer, Smith, nor Lu teach all the claimed elements either alone or in combination. Br. 4–6.

We are not persuaded. The test for obviousness is what the combined teachings of the references as a whole would have suggested to those of ordinary skill in the art. *In re Keller*, 642 F.2d 413, 425 (CCPA 1981). With the exception of using both internal and external reference frames as well as setting deviation thresholds, the Examiner finds that Dukesherer discloses all other claimed elements. *See* Ans. 4. Dukesherer teaches the use of a reference frame 54 that can be internally attached to the heart, as well as the use of multiple reference frames. FF3. Dukesherer also teaches that the reference frame 54 can be externally positioned. FF1, *see* Dukesherer ¶55. In addition to the use of one or multiple reference frames 54, Dukesherer also discloses the use of fiducial or artificial marks that serve as landmarks for the imaging data for the purpose of registration. FF7. Dukesherer's "electromagnetic tracking system 44 continuously recomputes the relative position of the dynamic reference frame 54 and the catheter 52 during localization and relates this spatial information to patient registration data to enable image guidance of the catheter 52 within the patient 14." FF5. Here, Dukesherer already discloses the option of using more than one reference frame and also teaches determining the location of both the reference frame and the catheter in the magnetic field. Even though the specific calculations are not disclosed in Dukesherer, Smith teaches that one way to locate the position of a catheter in a patient is through the use of triangulation algorithms that employ vector calculations to determine the location of the catheter tip in a patient. FF8; *see* Ans. 10 ("tracking of an object such as a catheter inserted into a patient").

The Examiner also acknowledges that Dukesherer and Smith do "not suggest specifically 'establishing a permitted threshold for a deviation of the location coordinates from the first range.'" Ans. 4. The Examiner relies on the teaching of Lu to establish setting deviation parameters for tracking patient movement. Dukesherer acknowledges that "[r]espiration and cardiac motion can cause movement of cardiac structures relative to the instrument 52, even when the instrument 52 has not been moved. Therefore, localization data may be acquired on a time-gated basis triggered by a physiological signal." Dukesherer ¶58. "Gating may also increase the navigational accuracy of the system 10." Dukesherer ¶56. "By time-gating or event gating at a point in a cycle the image data and/or the navigation data, the icon of the location of the catheter 52 relative to the heart at the same point in the cardiac cycle may be displayed on the display 36." Dukesherer ¶58. Thus, Dukesherer recognizes that physical movement can interfere with accurate navigation in the system, and in order to minimize error in the location of the catheter as it is displayed, one option is to acquire the localization data at the same time point in the cardiac cycle. This is one way of dealing with motion in the patient. The Examiner, however, looks to Lu for using another method to determine how to track an object in a moving target, e.g., a tumor in a patient's lung. FF9. Lu acknowledges that one "method of treating a moving target, such as a tumor of a lung, can include 'gating,' or delivering radiation only when the target is within a specified window of trajectory. This method is inefficient because the target is only being irradiated for periodic intervals of time." Lu ¶2. Lu teaches determining the anticipated motion of the object (the tumor) and applying a treatment track based on this motion. FF10. Lu's program includes multiple tracks each having a different deviation range based on a particular threshold. FF10. Lu teaches that the selection of the treatment plan is based on the selection of the track that most closely resembles the current breathing pattern of the patient. FF10. Both Dukesherer and Lu recognize that a patient's rhythmic motion such as breathing or cardiac rhythm can affect the accuracy of detecting the location of an object in the patient. Dukesherer's solution is to use gating while Lu's method accounts for the rhythmic motion but sets parameters so that when the rhythm changes, the object would no longer fall within the set parameters and an alternate treatment plan is then activated. We find no error with the Examiner's reliance on Lu for teaching that one of ordinary skill in the art could substitute one known technique for minimizing location error due to movement for another technique that also minimizes location error due to motion in the patient. "Express suggestion to substitute one equivalent for another need not be present to render such substitution obvious." *In re Fout*, 675 F.2d 297, 301, (CCPA 1982); *see also In re Mayne*, 104 F.3d 1339, 1340 (Fed. Cir. 1997) ("Because the applicants merely substituted one element known in the art for a known equivalent, this court affirms [the rejection for obviousness].").

Appellants contend that there is no suggestion or motivation in the art to modify Dukesherer, and even when combined with the other references there are no first and second range of location coordinates. Br. 6–10.

We are not persuaded. The Examiner explains that Dukesherer uses "the fixed frame of reference (when attached in either mode - external or internal) for collecting and processing first location coordinates of the internal reference probe in with respect to the fixed frame of reference, using the first position transducer, during one or more respiratory cycles of the subject so as to define a range of the location coordinates corresponding to the reference location." Ans. 3; FF4. Attaching the reference frame internally, for example to the wall of the patient's heart, "provides increased accuracy since this lead may track the regional motion of the heart." FF3. The Examiner finds that "the active device (52) is also located within the heart. Dukesherer also teaches collecting second location coordinates of the active device." Ans. 5; FF2, FF5 and FF6.

We conclude that the evidence cited by the Examiner supports a prima facie case of obviousness with respect to claim 1, and Appellants have not provided sufficient rebuttal evidence, or evidence of secondary considerations that outweighs the evidence supporting the prima facie case. As Appellants do not argue the claims separately, claims 3–6, 8–15, 17, and 18 fall with claim 1. 37 C.F.R. § 41.37 (c)(1)(iv). Because Appellants do not present additional arguments with respect to the rejection of claims 2 and 11 that relies on the additional reference of Slettenmark (*see* Br. 14) we affirm this rejection for the same reasons discussed with respect to claim 1.

SUMMARY

We affirm the rejection of claim 1 under 35 U.S.C. § 103(a) as unpatentable over Dukesherer in view of Smith in view of Lu. Claims 3–6, 8–15, 17, and 18 were not argued separately and fall with claim 1.

We affirm the claims 2 and 11 under 35 U.S.C. § 103(a) as unpatentable over Dukesherer, Smith, and Lu and further in view of Slettenmark.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED